BEYOND PESTICIDES
701 E Street, SE ▪ Washington DC 20003
202-543-5450 phone ▪ 202-543-4791 fax
info@beyondpesticides.org ▪ www.beyondpesticides.org

March 21, 2019

Environmental Protection Agency
OPP Docket
Environmental Protection Agency Docket Center (28221T)
1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Re: Docket # EPA-HQ-OPP-2018-0805

These comments are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers, and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Beyond Pesticides is writing to support the legally-grounded requests made in the **Petition Seeking Rulemaking or a Formal Agency Interpretation for Planted Seeds Treated With Systemic Insecticides (EPA-HQ-OPP-2018-0805)**. Beyond Pesticides supports the position of the Center for Food Safety that EPA has failed in its federal mandate to adequately assess and protect against the hazards posed by seed-delivered pesticide products, alternatively referred to as "treated seeds" or "coated seeds."

Overview

EPA's current practice of allowing seed-delivered pesticide products to escape pesticide regulation is a violation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. § 136a). Pesticide-coated seeds possess unique pesticidal and environmental fate properties that must be regulated under FIFRA to ensure adequate protection of the environment and public health. Documented exposures unique to treated seeds, for example through seed dust, soil, and groundwater leaching, have potentially far-reaching health consequences for pollinators, protected wildlife, and humans. Groundwater leaching of seed-delivered pesticide products, for example, must be separately assessed to ensure adequate protection of human health against the hazards of documented drinking water contamination.

Treated seeds fit the legal definition of and are explicitly marketed as pesticides. They, in fact, have pesticidal properties. Regardless of the regulatory interpretation of the Treated Article Exemption, it is the legal responsibility of EPA to regulate all pesticides in such a way as to prevent unreasonable adverse effects on the environment and public health. The Treated

Article Exemption itself must be questioned for its role in facilitating unlawful under-regulation of materials with clearly demonstrated and advertised pesticidal properties.

Both EPA's failure to regulate seed-delivered pesticides and EPA's acceptance of consequent mislabeling by seed-delivered pesticide producers and distributors are violations of FIFRA and must be promptly corrected to prevent further unreasonable harm to the environment and public health. EPA must consider the effects of the pesticides as they are used and intervene to prevent unreasonable adverse effects on human health and the environment. If a pesticide is distributed in the environment by means of a treated article, then EPA must regulate that distribution process. Exempting treated articles from full regulatory consideration does not allow EPA to fulfill its obligations. EPA may argue that treated articles are not "pesticides," but that does not relieve the agency from the obligation to regulate the use of the pesticide in/on an article that distributes the pesticide in the environment and promotes exposure to humans and other organisms.

FIFRA Registration Standards

FIFRA requires that all pesticides must be registered before sale or distribution.[1] The term "pesticide" is defined to include "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." Treated seeds fit this definition of a pesticide, given that the seeds are intended and explicitly marketed to destroy crop pests.

To register a pesticide with the U.S. Environmental Protection Agency (EPA), applicants must follow certain procedures and submit specific information and data concerning the makeup of the chemical, its intended uses, potential hazards, and adverse effects.[2] FIFRA mandates that EPA register a pesticide if, and only if, after review of the registration application and taking into account classification restrictions,[3] the pesticide meets four basic requirements:

(1) Its composition is such as to warrant the proposed claims for it;

(2) Its labeling and other material required to be submitted comply with FIFRA requirements;

(3) It will perform its intended function without unreasonable adverse effects on the environment; and

(4) When used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.[4]

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[1] 7 U.S.C. § 136a.

[2] 7 U.S.C. § 136a(c)(1) and (2); *see also* 40 C.F.R. §§ 159.165, 159.167, 159.70, 159.178, 159.179, 159.184, 159.188, 159.195.

[3] *See* 7 U.S.C. § 136a(d)(1)(A) ("As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use.")

[4] 7 U.S.C. § 136a(c)(5)(A)-(D).

Adverse effects to public health are integrated through the definitions section of FIFRA, wherein "unreasonable adverse effects on environment" is defined to include "[a]ny unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

If EPA finds that a pesticide does not meet one of the four registration requirements, EPA must notify the applicant of the unsatisfied requirement(s), allow for a 30-day correction period, and then may elect to deny the registration.[5]

Current Regulatory Practices: Treated Article Exemption

In violation of FIFRA's mandate to regulate all pesticides, EPA currently evades regulation of pesticidal treated seeds by claiming them as "treated articles" under 40 C.F.R. § 152.25(a), known as the Treated Article Exemption:

> *"§ 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.*
>
> *The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.*
>
> *(a) Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use."*[6]

Because EPA currently considers treated seeds as "treated articles," it fails to regulate seed-delivered pesticide products as required under FIFRA. The Treated Article Exemption itself is thus an unlawful regulatory instrument, used to evade FIFRA statute, and must not be allowed to justify the failure to regulate seed-delivered pesticide products.

Current regulatory practice as directed by EPA's interpretation of the law and use of an unlawful regulatory instrument, is in direct violation of FIFRA, 7 U.S.C. § 136a. While the chemicals used to coat seeds are tested according to regulation protocols, once the chemical is applied to a seed, any registration, labeling, or use restrictions typically required under FIFRA are not currently enforced by EPA. Thus, EPA does not currently assess adverse effects to the environment and public health wrought by widespread use of seed-delivered pesticides, which pose unique threats due to their unique modes of environmental exposure and toxicity, separate from those posed by application via spraying, drenching, or foliar treatment.

Treated Seeds Must be Regulated to Protect the Environment and Public Health

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[5] 7 U.S.C. § 136a(d).
[6] 40 C.F.R. § 152.25.

Treated seeds lead to unique exposures, such as through seed dust, and unique contamination of surrounding vegetation, soil, surface water, and groundwater. Seed-delivery of pesticides causes as yet under-studied changes in the amount of pesticide delivered through dust, soil, vegetation, and water, with far-reaching consequences for wildlife and human health.

Seed-delivered Pesticides Increase Extent and Magnitude of Neonicotinoid Use

Treated seeds are not only replacing but massively expanding the extent and magnitude of neonicotinoid use, relative to other methods of systemic pesticide application. The role of treated seeds in particular in increasing overall neonicotinoid contamination demands full assessment and regulation.

According to a recent review, "[T]ens of millions of hectares of cropland [are] planted with neonicotinoids annually."[7] The introduction and spread of seed-delivered pesticides to major field crops from 2003-2011 caused a massive increase in total neonicotinoid delivery nationwide; a 2015 review of USGS survey data found that 79 to 100% of maize acres and 34 to 44% of soybeans preemptively seed-treated with neonicotinoids by 2011, accounting for an astounding 35-fold increase in nationwide neonicotinoid use from baseline rates prior to 2003. Notably, seed-treatments accounted for "virtually all neonicotinoids applied to maize, soybeans, and wheat" during the period from 2000 to 2012, and the expansion in overall use was driven almost entirely by the introduction of seed treatments onto previously untreated "new acres".[8]

More recent analyses suggest that neonicotinoid use in corn has since expanded even further, with double the amount of neonicotinoids applied in corn in 2014 relative to the already massively increased uses documented in 2011. These recent increases must be due to increases in per-acre use, given that nearly 100% of corn acres were already seed-treated by 2011.[7] As of 2014, total neonicotinoid use in the US was estimated at 3.47 million kg, representing a 46-fold increase over pre-2003 annual application rates.[7]

Alarmingly, because the national pesticide survey conducted by the National Agricultural Statistics Service fails to include by-now ubiquitous seed-applied neonicotinoids, its reports give the misleading impression that neonicotinoid use has declined over the past few decades. Douglas and Tooker note that this lack of data collection on treated seed use leads to unacceptable risk assessment knowledge gaps, stating,

> *"The void of information on seed treatments also challenges researchers and regulators seeking to assess environmental contamination and potential nontarget effects associated with neonicotinoids, areas of increasing concern... Characterizing the risk*

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[7] Tooker, J.F., Douglas, M.R. and Krupke, C.H., 2017. Neonicotinoid seed treatments: limitations and compatibility with integrated pest management. *Agricultural & Environmental Letters*, *2*(1).

[8] Douglas, M.R. and Tooker, J.F. 2015. Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops. *Environmental Science and Technology* doi: 10.1021/es506141g.

posed by neonicotinoids to nontarget species obviously requires understanding where and how these compounds are used."

Seed-delivered technologies have dramatically altered the landscape of pesticide use and pesticide contamination in the U.S.; their continued under-regulation is in violation of EPA's federal mandate to regulate and fully assess the risks posed by pesticides, as they are commonly applied.

Seed-delivered Pesticides Increase Proportion and Total Mass of Applied Neonicotinoids Contaminating Soil and Water

On top of causing massive increases in the total extent and per-acre rate of neonicotinoid application, seed treatments increase the proportion of neonicotinoids applied that enter into soil and groundwater.

A large portion of the pesticide delivered through seeds exits the coating and enters into the surrounding air, soil, and water. A study of treated seed uptake across several common crop types found that only 1.5-5% of imidacloprid delivered through seed treatment in cotton, eggplant, potato, and rice is taken up by the plants; the rest is lost to seed dust or leached into soil and groundwater.[9] While a potted plant study of imidacloprid seed treatment in corn found that 20% of the insecticide was taken up by plants, a two-year field study of clothianidin seed treatment in corn found that only at most 1.6% of the total applied compound was present in plant and root tissues in the weeks following planting.[10] These pesticide- and environment-dependent measures indicate a need for full field assessment of the unique environmental exposures wrought by each new seed treatment product.

Applying pesticides through seed-delivered technologies releases large amounts of neonicotinoids into soils and waterways; using a conservative estimate of 80% pesticide leaching,[9,11] and assuming the 2014 nationwide annual application rate of 3.47 billion kilograms (as reported by USGS),[7] we estimate that *treated seeds deliver at least 2.77 million kilograms of neonicotinoids into soil and water every year.*

Seed treatment causes additional, unique exposures due to the release of contaminated seed dust abraded during mechanical planting.[10] Notably, neonicotinoid contamination through seed dust poses a direct threat to pollinators by increasing potential contact exposure during seed planting.[12]

Pollinators are further negatively impacted by increased exposure to neonicotinoids in guttation droplets, as a direct result of seed treatment. Girolami et al. 2009 found that applying

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[9] Sur, R. and Stork, A. 2003. Uptake, translocation and metabolism of imidacloprid in plants. *Bulletin of Insectology* 56 (1): 35-40.

[10] Alford, A. and Krupke, C.H., 2017. Translocation of the neonicotinoid seed treatment clothianidin in maize. *PloS one*, *12*(3), p.e0173836.

[11] Hladik, M.L., Main, A.R. and Goulson, D., 2018. Environmental risks and challenges associated with neonicotinoid insecticides.

pesticides through coated seeds can lead to higher concentrations of neonicotinoids in plant guttation droplets than would result from applying field sprays, leading to higher exposures for pollinators and other non-target insects.[12] Moreover, each different insecticide was found to have a unique and dose-dependent profile of transport from seed coating into guttation droplets, highlighting the need for separate data review for each coated seed product.

Seed-delivered Pesticides Pose Unique Threats to Wildlife

Seed-delivered technologies possess unique pesticidal properties and lead to unique exposures that significantly alter the toxicology of the full pesticide product. Thus it is imperative that their use is accurately monitored and regulated, as mandated under FIFRA.

By altering potential exposures to neonicotinoids, treated seeds pose unique threats to wildlife. Seed-treatment neonicotinoids first enter the environment during sowing, when contaminated dust from treated seeds is released into the air and may settle directly onto foraging pollinators, as well as into surrounding soil and vegetation.[13,14] After sowing, bees and other pollinators can be exposed to seed-treatment neonicotinoids via two routes. First, residues can reach bordering crops and wildflowers via leaching into the soil and wind-blown contaminated dust.[15,16] Second, because neonicotinoids are systemic insecticides, they are taken up by plant tissue and can be found in all parts of a treated plant, including pollen.[17]

Treated seeds pose unique threats to pollinators, above and beyond those posed by neonicotinoids otherwise delivered. Several independent studies have confirmed that bees are exposed to unacceptably high levels of neonicotinoid insecticides during spring planting of treated seeds, leading to documented mass honey bee poisonings.[17] Neonicotinoids in abraded seed dust can reach concentrations as high as 240,000 ng/g, or four to five orders of magnitude higher than the acute contact LD_{50} values of common neonicotinoids.[18]

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[12] Girolami, V. et al. 2009. Translocation of Neonicotinoid Insecticides From Coated Seeds to Seedling Guttation Drops: A Novel Way of Intoxication for Bees. *Journal of Economic Entomology*: https://doi.org/10.1603/029.102.0511.

[13] Krupke, C.H., Hunt, G.J., Eitzer, B.D., Andino, G. and Given, K., 2012. Multiple routes of pesticide exposure for honey bees living near agricultural fields. *PLoS one*, *7*(1), p.e29268.

[14] Tapparo, A., Marton, D., Giorio, C., Zanella, A., Soldà, L., Marzaro, M., Vivan, L. and Girolami, V., 2012. Assessment of the environmental exposure of honeybees to particulate matter containing neonicotinoid insecticides coming from corn coated seeds. *Environmental science & technology*, *46*(5), pp.2592-2599.

[15] Botías, C., David, A., Horwood, J., Abdul-Sada, A., Nicholls, E., Hill, E. and Goulson, D., 2015. Neonicotinoid residues in wildflowers, a potential route of chronic exposure for bees. *Environmental science & technology*, *49*(21), pp.12731-12740.

[16] Wu-Smart, J. and Spivak, M., 2016. Sub-lethal effects of dietary neonicotinoid insecticide exposure on honey bee queen fecundity and colony development. *Scientific reports*, *6*, p.32108.

[17] Simon-Delso, N., Amaral-Rogers, V., Belzunces, L.P., Bonmatin, J.M., Chagnon, M., Downs, C., Furlan, L., Gibbons, D.W., Giorio, C., Girolami, V. and Goulson, D., 2015. Systemic insecticides (neonicotinoids and fipronil): trends, uses, mode of action and metabolites. *Environmental Science and Pollution Research*, *22*(1), pp.5-34.

[18] Wood, T.J. and Goulson, D., 2017. The environmental risks of neonicotinoid pesticides: a review of the evidence post 2013. *Environmental Science and Pollution Research*, *24*(21), pp.17285-17325.

In a 2012 study by researchers at the University of Padova in Italy, researchers found that exhaust from treated corn seed planters contained high amounts of neonicotinoids and that bees are exposed to these potentially lethal concentrations of the chemical simply by flying through the area during planting.[12] Study authors found concentrations of clothianidin and thiamethoxam in and on flying bees that are "significantly higher" than known lethal doses. The study includes analyses of several different kinds of seed coatings as well as seed planting machines, but the team found that no modifications to seeds or planters result in any significant decrease in the emission of chemical dust or the contamination levels of the bees themselves. In conclusion, the authors note that,

> *"This emission source of particles with acute toxic effects on bees (and on other insects too) is of concern for both apiculture and crop productions based on bee pollination. But it is also a widespread ecological problem that, in view of the worldwide increase in corn production partly promoted by government subsidies to renewable energy sources, and the consequent predictable exacerbation of the problem, should require a deeper analysis of the related agricultural policies."*

This new route of exposure through seed planter dust was previously demonstrated in the work of Dr. Christian Krupke, Ph.D. at Purdue University.[19] In that study, researchers found that, during the spring planting season, there are extremely high levels of both clothianidin and thiamethoxam in planter exhaust material produced during the planting of seed treated corn. The field soil was also found to be contaminated with these neonicotinoids, including unplanted fields. Plants visited by foraging bees, including dandelions growing near these fields, were found to contain neonicotinoids as well. According to the Purdue research team, this indicates deposition of neonicotinoids on the flowers, uptake by the root system, or both. During the spring, when neonicotinoid levels are highest, dead bees collected near hive entrances were found to be contaminated with clothianidin, although whether exposure was oral (consuming pollen) or by contact (soil/planter dust) is unclear. Clothianidin was also detected in pollen collected by bees and stored in the hive. This growing body of scientific evidence attests to the need for full evaluation and labeling of treated seeds in particular, as they pose unique threats that cannot be adequately assessed by way of the chemicals they deliver alone. Inaction by EPA has led state regulators to avoid investigating bee deaths from exposure to dust from planting seeds treated with neonicotinoid insecticides.

Neonicotinoid-treated seeds pose far-reaching risks to wildlife, above and beyond those posed by neonicotinoids delivered in other forms. In EPA's 2017 ecological assessment of neonicotinoids, treated seeds in particular were identified as posing the highest dietary risks to birds. EPA scientists found that risks posed to certain birds from eating neonicotinoid-treated seeds exceed the agency's level of concern as much as 200-fold. Even slight deviations in exposure levels take a heavy toll on vulnerable wildlife. Researchers at the University of

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[19] Krupke, C.H., Hunt, G.J., Eitzer, B.D., Andino, G. and Given, K., 2012. Multiple routes of pesticide exposure for honey bees living near agricultural fields. *PLoS one*, *7*(1), p.e29268.

Saskatchewan have found that tiny amounts of neonicotinoids – the equivalent of just four treated canola seeds, for example – are enough to cause migrating songbirds to lose their sense of direction and become emaciated.[20]

There is substantial evidence that neonicotinoid-treated seeds cause unreasonable harm to aquatic invertebrates – the foundation of healthy aquatic ecosystems. An EPA Aquatic Risk Assessment for imidacloprid, released in 2017, found that imidacloprid threatens the health of U.S. waterways with significant risks to aquatic insects and cascading effects on aquatic food webs.[21] In a 2018 study by USGS, researchers found neonicotinoids widespread throughout the Great Lakes at levels known to harm aquatic insects.[22] A similar study of Midwestern surface waters, conducted by USGS in 2014, found at least one neonicotinoid in 76% of samples from high-intensity agricultural land, and 53% of samples from mixed land use areas.[23] With high frequency detections and maximum concentrations of clothianidin, thiamethoxam, and imidacloprid at 257, 185, and 42.7 nanograms per liter, respectively, researchers concluded that "concentrations may frequently exceed chronic aquatic toxicity values during [the] growing season."

Neonicotinoids that leach off of treated seeds have demonstrated toxicity to mammals, including large mammals, at levels consistent with widespread environmental concentrations. A 2019 controlled study conducted by researchers at South Dakota State University and the North Dakota Game and Fish Department found that field-relevant levels of imidacloprid contamination in the organs of white-tailed deer were predictive of low body weight, reduced metabolism, and mortality in fawns. Remarkably, researchers found that the levels of the pesticides in concurrently sampled free-ranging deer in North Dakota (n = 367) are a full 3.5 times higher than the mortality-linked levels induced in treated animals. In fact, 77.5% of the free-ranging deer sampled have spleen levels of imidacloprid greater than 0.33 ng/g – the mean level detected in the spleens of fawns that died in the experiment. Moreover, the average concentration of imidacloprid in free-ranging deer increased by an average of 0.11 ng/g per year from 2009 to 2017, concomitant with a more than 2.6-fold increase in the use of neonicotinoid-treated seeds in corn, soy, and other major crops during that period.

Seed-delivered Pesticides Pose Unique Threats to Public Health

In addition to threatening wildlife, the widespread use of neonicotinoid-treated seeds also puts human health at risk. The mass leaching of seed-delivered pesticides may lead to unreasonable adverse effects on public health via contamination of drinking water. A recent

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[20] Eng, M.L., Stutchbury, B.J. and Morrissey, C.A., 2017. Imidacloprid and chlorpyrifos insecticides impair migratory ability in a seed-eating songbird. *Scientific reports*, *7*(1), p.15176.

[21] US EPA, 2016. Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid. Available: regulations.gov, Docket # EPA-HQ-OPP-2008-0844-1086.

[22] Hladik, M.L., Corsi, S.R., Kolpin, D.W., Baldwin, A.K., Blackwell, B.R. and Cavallin, J.E., 2018. Year-round presence of neonicotinoid insecticides in tributaries to the Great Lakes, USA. *Environmental pollution*, *235*, pp.1022-1029.

[23] Hladik, M.L., Kolpin, D.W. and Kuivila, K.M., 2014. Widespread occurrence of neonicotinoid insecticides in streams in a high corn and soybean producing region, USA. *Environmental pollution*, *193*, pp.189-196.

study by researchers at USGS and the University of Iowa found the neonicotinoid insecticides clothianidin, imidacloprid, and thiamethoxam were detected in 100% of analyzed samples of finished drinking water collected from taps in three locations in Iowa City, IA.[24] Authors state, "Because of their pervasiveness in source waters and persistence through treatment systems, neonicotinoids are likely present in other drinking water systems across the United States."

Of note, researchers found that finished drinking water frequently contains metabolites of the commonly seed-applied neonicotinoid imidacloprid that have never been evaluated for their potential risks to human and environmental health. Experts warn that these metabolites may morph further into new forms of chlorinated disinfection byproducts during routine water treatment processes, with potential for high toxicity to humans due to loss of insect specificity. For example, according to the study authors, the potential transformation product desnitro-imidacloprid "exhibits a mammalian receptor binding affinity 300 times greater than that of imidacloprid because of the loss of the nitro group that confers insect specificity."

An independent study of neonicotinoid levels in six water treatment plants in Ontario, Canada, found thiamethoxam and imidacloprid in all of the raw samples and more than half of treated drinking water samples[25]. Authors pointed to a concerning lack of adequate data on potentially high-toxicity chlorination bi-products of neonicotinoids likely pervasive in treated drinking water. Available data suggests a deeper need for assessment to ensure adequate protection of the environment and public health.

Treated Seeds are Marketed as Pesticides, and Must be Regulated as Pesticides

Treated seeds meet the definition of pesticides under FIFRA, and therefore must be regulated and labeled to ensure that their use does not cause unreasonable harm to the environment and public health. The use of the Treated Article Exemption (TAE) to evade such regulation is unlawful.

FIFRA mandates the regulation and labeling of "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." EPA's interpretation of a pesticide is "any substance (or mixture of substances) intended for a pesticidal purpose," further clarified in 40 C.F.R. § 152.15:

> *"A substance is considered to be intended for pesticidal purpose, and thus to be a pesticide requiring registration, if:*
>
> *(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):*
>
> *1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or*

[24] Klarich, K.L. et al. 2017. Occurrence of Neonicotinoid Insecticides in Finished Drinking Water and Fate during Drinking Water Treatment. *Environmental Science and Technology Letters* doi: 10.1020/acs.estlett.7b00081.
[25] Sultana, T., Murray, C., Kleywegt, S. and Metcalfe, C.D., 2018. Neonicotinoid pesticides in drinking water in agricultural regions of southern Ontario, Canada. *Chemosphere*, *202*, pp.506-513.

2) *That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or*

(b) *The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or*

(c) *The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose."*

Treated seeds contained active ingredients used for pesticidal purposes, and are distributed and sold by companies that acknowledge and claim that the seeds will be used for pesticidal purpose. Chemical companies routinely advertise seed treatments as "seed-applied insecticides" intended for destroying pests of the growing and fully developed plant, as seen in the following examples [emphasis added]:

- DuPont™ advertises that the product Lumisena™ fungicide seed treatment controls "Phytophthora in soybeans and downy mildew in sunflower crops."[26] According to a DuPont™ fact sheet, "Phytophthora fungus can kill plants at all stages of growth." Referring to the active ingredient in Lumisena™, DuPont's™ technical product release[27] states, "Research studies show that oxathiapiprolin ***provides outstanding protection for soybean seeds and young plants*** against *Phytophthora*..." As stated in the document, ***the seed treatment's "[s]ystemic control improves root and plant health."***

- DuPont™ advertises the corn seed treatment Lumivia™ as an insecticide that is applied by way of the seed in order to protect corn.[28] "Lumivia™ insecticide seed treatment ***is a convenient seed-applied insecticide for corn*** that is part of the DuPont™ Lumigen™ seed sense family of products." DuPont™ advertises that the seed treatment provides protection of corn "from insects including wireworms, white grubs, black cutworms, seed corn maggot and fall armyworm...," all pests of corn which can infest plants at multiple stages of development.

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[26] DuPont, 2016. Lumisena™ Fungicide Seed Treatment for Soybeans, Sunflowers: http://www.dupont.com/products-and-services/crop-protection/seed-treatment/press-releases/fungicide-seed-treatment.html.

[27] DuPont Technical Bulletin, 2012. DuPont™ Lumisena™ fungicide seed treatment: http://www.dupont.com/content/dam/dupont/products-and-services/crop-protection/documents/en_us/cp_PSD-125_Lumisena_soybean_technical_bulletin.pdf.

[28] DuPont™ Lumivia™ Insecticide Treatment: Protect Your Success with Effective Insecticide Corn Seed Treatment. http://www.dupont.com/products-and-services/crop-protection/corn-protection/products/lumivia.html.

- In their advertisement for the rice seed treatment Dermacor® X-100[29], DuPont™ states, "DuPont™ Dermacor® X-100 seed treatment works immediately to ***protect rice against damage from rice water weevil and later-season stemborers…***"

EPA Policy Changes Needed to Fulfill Mandate Under FIFRA

Seed treatment leads to unique exposures that differ from those induced by spraying, drenching or otherwise delivering pesticides to crops. These unique exposures demand full assessment and regulation to prevent unreasonable harms to wildlife and human health.

EPA must ensure that pesticides do not cause unreasonable adverse effects to human health and the environment by assessing the effects of the pesticides as they are commonly used. If a pesticide is distributed in the environment by means of a treated article, then EPA must regulate that distribution process. Exempting treated articles from consideration does not allow EPA to fulfill its obligations. EPA may argue that treated articles are not "pesticides," but that does not relieve the agency from the obligation to regulate the use of the pesticide in/on an article that distributes the pesticide in the environment and promotes exposure to humans and other organisms.

In order to comply with FIFRA, EPA must require applicants for coated seed pesticide products to submit all required data in support of registration, including specific routes of exposure of seed-delivered pesticides. Likewise, farmers who apply the seed-delivered pesticides must receive adequate labeling instruction on proper application methods as required under FIFRA, and must be subject to enforcement under FIFRA should they fail to comply with application standards. Lastly, registrants must be required to publish notice of new treated seed pesticide products for public comment to ensure transparency and accountability around new potential hazards to the environment and public health.

Please consider the real cost to the American people and to our ecosystem, and regulate treated seeds as required of all pesticidal products, in accordance with FIFRA.

Thank you for your consideration of these comments.

Sincerely,

Sarah Bluher
Science and Regulatory Manager

Terry Shistar, Ph.D.
Board of Directors

[29] DuPont™ Dermacor® X-100 Seed Treatment: Suppress Grape Coalspis* to Avoid Yield-Robbing Insect Damage. http://www.dupont.com/products-and-services/crop-protection/rice-peanut-tobacco-protection/products/dermacor-x-100.html.